Testing of Cineraria Maritima Eye Drop for Efficacy

1441. SHRI SUDHIR RANJAN MAJUMDAR : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether the 'Cineraria Maritima' eye drops, a homeopathic medicine which is being imported, has been tested for efficacy by clinical trial as required under Rule 10AA of Drugs and Cosmetics Act, 1940;

(b) if so, the details thereof; and

(c) if not, how Government have satisfied itself in accordance with the provisions of the Act ?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI D. K. THARA DEVI SIDDHARTHA) : (a) to (c) It is presumed that Hon'ble Member of Parliament is referring to Rule 30 AA, as Rule 10 AA does not exist in the Drugs and Cosmatics Rules 1945, framed under the Drugs and Cosmetic Act, 1940. The Rule 30 AA is given in the statement [see below]. From its perusal it is seen that the licensing authority is required only to assess the therapeutic efficiency of the medicines on the basis of the documents and other evidences submitted by the Importer, when applying for permission. Accordingly the licensing authority having satisfied about its efficacy, granted permission for the Import of Cineraria Maritima eye drops.

Statement

The Drugs and Cosmetics Act, 1940

and

The Drugs and Cosmetics Rules, 1945

30 AA. IMPORTANT OF NEW HOMOEOPATHIC MEDICINE—(1) No New Homoeopathic medicine shall be imported except under and in accordance with permission in writing of the licensing authority.

(2) The importer of a New Homoeopathic Medicine when applying for permission shall produce before the licensing authority such documentary and other evidence as may be required by the licensing authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.

Explaination—For the purpose of this rule, 'New Homoeopathic Medicine' means—

(i) a Homoeopathic medicine which is not specified in the Homoeopathic pharmacopoeia of India or the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia; or

(ii) which is not recognised in authoritative Homoeopathic literature as efficacious under the conditions recommended; or

(iii) a combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) as Homoeopathic medicines and also not recognised in authoritative Homoeopathic Literature as efficacious under the conditions recommended;

Ban on the Import of Cineraria Maritima

1442. SHRI SUDHIR RANJAN MAJUMDAR : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether Government have recently considered the question of imposing ban on the import of Cineraria Maritima, a homoeopathic medicine; and

(b) if so, the details thereof ?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI D. K. THARA DEVI SIDDHARTHA) : (a) and (b) A meeting was convened under the chairmanship of Minister of State for Health & Family Welfare to discuss the various issues relating to Import of Cineraria Maritima Succus/Cineraria Maritima eye drop on 19th October, 1992 in New Delhi. The question of banning of Import of Cineraria Maritima eye drop was also raised in the said meeting. However, no such view could be taken in the meeting and it was felt that this needs further consideration.